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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/573,176 | 03/23/2006 | Wolfgang Stachle | MERCK3155 | 6633 |
| 23599 7590 12/07/2009 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201 | | | | |
| EXAMINER | | | | |
| FIERRO, ALICIA | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1626 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 12/07/2009 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary

Application No.

10/573,176

Applicant(s)

STAEHLE ET AL.

Examiner

Alicia L. Fierro

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14-38 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 14-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 9 and 30-37 is/are rejected.
- 7) ☒ Claim(s) 4, 7, 8, 10, 11 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date (2).
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-11 and 14-38 are currently pending in the instant application. Claims 6 and 14-29 remain withdrawn for being drawn to a non-elected species/invention.

Response to Amendments and Arguments

2. Applicant's arguments and amendments filed July 20, 2009 have been fully considered and entered into the application. All rejections and objections not explicitly maintained herein are withdrawn.

3. Applicants again traverse the restriction requirement, which has already been made **final** for the reasons of record in the office action dated February 20, 2009. The Examiner maintains that the restriction requirement was made properly. Applicants cite section (f) of Annex B, stating that the alternatives will be regarded as fulfilling the criteria of being of a similar nature if the alternatives have a common property/activity and have a common significant structural element. The Examiner disagrees with Applicants assertion that all compounds in the Markush grouping set forth as formula I share a "chemical structure which occupies a large portion of their structures." Because of the great variation in variables R^1 , R^2 , R^3 and Y, the amino linked two-ring system common to all compounds does not constitute a large portion of the chemical structure. Based on the possibilities for substitution, each of the above variables could encompass several more rings in addition to the core structure shown in formula I. For example, R^1 , R^2 and R^3 could each be NHR where R is Het (an aromatic heterocycle) and R is further substituted by $-(CH_2)_b-Ar$, where Ar is phenyl. Considering the substitution at each of the three R

positions, this compound has 6 rings in addition to the core structure defined in claim 1.

Therefore, the structural element shared by all compounds of formula I cannot be considered a significant structural element in light of how large the compounds can be. The finality of the restriction requirement is therefore **maintained**.

4. Applicants also argue with the Examiner's interpretation of the claim limitations in the office action dated February 20, 2009. Specifically, the claims recited the term "derivatives." Applicants argue that, read in light of the specification, the claims could not have been interpreted to read on carbon dioxide. However, it is noted that, as explained in the previously issued office action, no explicit definition for "derivatives" was provided in the specification. Examples were given to suggest that the term would *include* salts and pro-drugs, but these are non-limiting examples. An appropriate definition of the term derivative was applied in the 102 rejection (i.e. "a substance that can be made from another substance," Merriam-Webster Dictionary). When given its broadest reasonable interpretation, absent any specific structural information on the claimed "derivatives," the term reads on carbon dioxide. Although the claims are read in light of the specification, limitations from the specification are not imported into the claims. Since no explicit definition or structural information was provided for the claimed derivatives the Examiner maintains that an appropriate interpretation of the claims was made in the previously issued office action.

5. Applicant's claim amendments overcome the previous rejection made under 35 U.S.C. 102(b). In accordance with MPEP 803.02, the amended claims will be reexamined and the prior art search extended to the extent necessary to determine patentability of the Markush-type claim. The search was extended to a compound of Formula (I) wherein $R^1=R^2=R$ wherein R is H;

$n=m=1$; X is O; Y is phenyl; R^3 is NHR where R is Het and Het is a bicyclic aromatic heterocycle having 2 N atoms which is unsubstituted (benzimidazol-2-yl); and $p=1$. Because this species was not found allowable, the search was not extended further and the Markush claim was rejected.

Information Disclosure Statement

6. The information disclosure statements (IDS) submitted on March 23, 2006 and July 20, 2009 were in compliance with the provisions of 37 CFR 1.97 and 37 CFR 1.98. The IDS documents were considered. Signed copies of form 1449 are enclosed herewith. The Examiner regrets any inconvenience caused by the failure to include a signed copy of the 1449 with the previously issued office action.

Maintained Objections

7. Claims 1-5, 7-11 and 30-38 are objected to for containing non-elected subject matter. This objection can be overcome by submitting an amendment deleting the non-elected subject matter.
8. Claims 4, 7, 8, 10, 11 and 38 are objected to for being dependent upon a rejected base claim, but would not necessarily be allowable if rewritten in independent form.

New Claim Rejections- 35 U.S.C. § 102

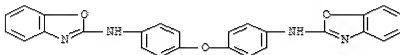
9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3, 5, 9, and 30-37 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Garin et al, *J. Het Chem.* (1990), 27(2), pp. 221-226.

Garin et al. teaches the following compound which is identical to the instantly examined species, wherein the substituents are identified in paragraph 5 above. The compound is taught as compound 6d on page 221 of the reference. The compound has the following structure (provided by CAPlus, STN search):



The reference also teaches that the compounds were washed with water, ethanol and ether and subsequently recrystallized from the appropriate solvent (p. 224, left column, Method B), so the instantly claimed pharmaceutical composition comprising a compound of formula (I) and one or more excipients and/or adjuvants is also anticipated.

Conclusion

11. No claims are allowed

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia L. Fierro whose telephone number is (571)270-7683. The examiner can normally be reached on Monday - Thursday 6:00-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

10. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

/Alicia L. Fierro/

Examiner, Art Unit 1626

/REI-TSANG SHIAO /

Primary Examiner, Art Unit 1628